#5 6/7/02 AM #5

Attorney Docket No.: **FSTK 1004-1**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	PATENT APPLICATION
Inventors: **Michael G. Kahn et al.**	
SC/Serial No.: **09/974,781**	Group Art Unit: **2166**
Confirm. No.: **8124**	
Filed: **10 October 2001**	**Customer No. 22470**
Title: **CLINICAL TRIAL PROTOCOL QUALITY USING A MODEL-BASED METHODOLOGY**	

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.56

Commissioner for Patents
Washington, DC 20231

Sir:

It is requested that the information identified in this statement be considered by the Examiner and made of record in the above-identified application. This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56. It is understood that the Examiner will consider all information which was considered by the Office in the parent application. MPEP §609. Such information therefore is not listed herein unless it is desired that the information be printed on a patent issuing from the subject application.

Enclosed with this statement are the following:

1. Form PTO-1449. The Examiner is requested to initial the form and return it to the undersigned in accordance with M.P.E.P. §609.

2. A copy of each cited document as required by 37 C.F.R. §1.98. Copies are not submitted of documents previously submitted by the applicant in a parent application from which benefit under 35 U.S.C. §120 is claimed, 37 C.F.R. §1.98(d)(1), with an information disclosure statement submitted in the parent application which complies with the Sept. 8, 2000 or subsequent revision of 37 C.F.R. §1.98(a-c).

This statement should be considered because it qualifies under 37 C.F.R. §1.97(b) as having been filed before the mailing date of the first Office Action on the merits. No fee is due for the filing of this Information Disclosure Statement.

✓ ***Fee Authorization.*** The Commissioner is hereby authorized to charge underpayment of any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-0869 (FSTK 1004-1). A duplicate copy of this authorization is enclosed.

Respectfully submitted,
HAYNES BEFFEL & WOLFELD LLP

Date: 1/25/2002

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	09/974,781
Filing Date	10 October 2001
First Named Inventor	Michael G. Kahn
Group Art Unit	2166
Examiner Name	Unknown
Attorney Docket Number	FSTK 1004-1

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	C1	DataEdge LLC. Indexes of Clinical Study Complexity, 1993-1999. In: Mathieu MP, editor. Parexel's Pharmaceutical R&D Statistical Sourcebook 2000. Waltham, MA: Parexel International Corp; 2000. p. 66.	
	C2	DataEdge LLC. Indexes of Clinical Trial Costs Per Patient, 1993-1999. In: Mathieu MP, editor. Parexel's Pharmaceutical R&D Statistical Sourcebook 2000. Waltham, MA: Parexel International Corp; 2000. p. 67.	
	C3	GROSSO W. E. et al.; "Knowledge Modeling at the Millennium (The Design and Evolution of Protégé-2000)," SMI Report Number: SMI-1999-0801 (1999), available at http://smi-web.stanford.edu/ pubs/SMI_Abstracts/SMI-1999-0801.html, visited 01/01/2000.	
	C4	HOLFORD N. H. G.; KIMKO H. C.; MONTELEONE J. P. R., and PECK C. C.; "Simulation of Clinical Trials," Annu. Rev. Pharmacol. Toxicol. 2000, 40:209-34, 2000, Annual Reviews.	
	C5	"ICH Harmonised Tripartite Guideline: General Considerations for Clinical Trials," International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use recommended for adoption on 17 July 1997, URL: www.ifpma.org/ich5e.html, Accessed: 31 August 2001.	
	C6	"ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice," International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use recommended for adoption on 1 May 1996 , URL: www.ifphma.org/ich5e.html, Accessed: 31 August 2001.	
	C7	KROLL J. A.; DE BRUIN A.; GETZ K.; ESCHMANN K.; and ZISSON S.; "Study Conduct Delays are Getting Worse," In: Kroll JA, editor. An Industry In Evolution. Second ed. Boston, MA: CenterWatch; 1999. p. 99.	
	C8	MUSEN M. A.; "Domain Ontologies in Software Engineering: Use of Protégé with the EON Architecture," Methods of Information in Medicine, F. K. Schattauer Verlagsgesellschaft mbH (1998); 37:540-50.	
	C9	MUSEN M. A.; GENNARI J. H.; ERIKSSON H.; TU S. W.; and PUERTA A. R.; Protégé-II: Computer Support for Development of Intelligent Systems from Libraries of Components," MEDINFO 95 Proceedings. R. A. Greenes et al. (editors); 8(1):766-70.	
	C10	MUSEN M. A.; ROHN J. A.; FAGAN L. M.; and SHORTLIFFE E. H.; "Knowledge Engineering for a Clinical Trial Advice System: Uncovering Errors in Protocol Specification," Report KSL-85-51, Proceedings AAMSI Congress 1986 (Levy, A.H. and Williams, B.T., eds.), pp. 24-27, Anaheim CA, May 1986.	
	C11	SHEINER L. B. and STEIMER J. L.; "Pharmacokinetic/Pharmacodynamic Modeling in Drug Development," Annu. Rev. Pharmacol. Toxicol. 2000. 40:67-95, 2000, Annual Reviews.	

Examiner Signature		Date Considered	

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Sheet 2 of 2

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First Named Inventor	Michael G. Kahn
Group Art Unit	2166
Examiner Name	Unknown
Attorney Docket Number	FSTK 1004-1

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	C12	WAMPLER S., "Tackling Protocol Complexity," Good Clinical Practice Journal, 2000; Vol. 7, No. 2: pp. 6-8.	

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